

Jerry G. Blaivas, M.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST  
VIRGINIA, CHARLESTON DIVISION

- - -

IN RE: BOSTON SCIENTIFIC :MDL NO. 2326  
CORP., PELVIC REPAIR SYSTEM:  
PRODUCTS LIABILITY :  
LITIGATION :

-----  
THIS DOCUMENT RELATES TO:  
ALL WAVE 1 AND 2 CASES IN MDL NO. 2326

- - -

December 4, 2014

- - -

Videotaped deposition of  
JERRY G. BLAIVAS, M.D., held in the  
offices of Motley Rice, LLC, 600 Third  
Avenue, Suite 2101, New York, New York  
10016, commencing at 9:10 a.m., on the  
above date, before Margaret Peoples, a  
Registered Professional Reporter and  
Notary Public in and for the States of  
Pennsylvania, New York and Connecticut.

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1 recollection of that, of being given  
2 trocars and asking what I thought, so is  
3 the thought -- sort of as a consultant  
4 and/or thought leader in a group of  
5 people.

6 So I have done that. And my  
7 comments, quite honestly, then were  
8 pretty much the same.

9 I definitely remember doing  
10 it with American Medical Systems. And I  
11 think I did it with Boston Scientific,  
12 but I can't be sure of that.

13 Q. Do I understand correctly  
14 that you have never used the trocars for  
15 the Obtryx, Lynx, or Advantage to  
16 actually implant those devices in a human  
17 being?

18 A. That's correct.

19 Q. Now, you gave -- I think the  
20 last time you gave a fairly long  
21 deposition for these cases was in the  
22 January to April time frame of this year.

23 A. Of?

24 Q. Of 2014.

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1 that Ross does unique examinations?

2 MS. FITZPATRICK: Objection.

3 THE WITNESS: I think it's  
4 plausible that Ross does a more  
5 thorough examination with respect  
6 to detecting banding than most  
7 other people do. Yes, I think  
8 that's plausible.

9 BY MR. MYERS:

10 Q. But you have no evidence to  
11 demonstrate that, correct?

12 A. I'm just answering your  
13 question. No, I don't.

14 Q. So at this point in the  
15 deposition, you have been shown I think  
16 that AUGS and SUFU and IUGA and the FDA  
17 have all issued statements in support of  
18 the use and the safety of mid-urethral  
19 slings. Is there any data that you could  
20 be shown that would change your opinion?

21 A. My opinion with respect to  
22 what?

23 Q. The safety of mid-urethral  
24 slings.

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1           A.     No, I don't even think we  
2     disagree about it. We dis -- as I've  
3     already testified, I think the people  
4     that wrote those articles would agree  
5     pretty much with my -- with the  
6     statistics that I have quoted. What they  
7     seem to disagree with is about how  
8     relevant that is to disclose that to  
9     patients. And I think that's a huge part  
10    of the problem, that it wasn't disclosed.

11                I don't think we disagree  
12    very much on this. I mean, we may  
13    quibble over percentage points whether  
14    it's one, two, three, four, five, six,  
15    but no one is going to say -- I would  
16    venture to say no one is going to say  
17    these lifestyle altering complications do  
18    not occur. Practically no one.

19           Q.     I'm pretty confident that  
20    I'm not going to look on your website  
21    tomorrow and find a statement saying Dr.  
22    Blaivas supports the use of mid-urethral  
23    slings for stress urinary incontinence;  
24    is that correct?

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1           Q.     And I'm trying to understand  
2     the disconnect between you saying you  
3     think they agree with everything you say  
4     and yet they can make the statement that  
5     they recommend the use of the products.  
6     Are they reckless in your opinion about  
7     harm to patients?

8           A.     I think we -- I think I have  
9     already testified. I think we just have  
10    a disagreement about how relevant it is  
11    that lifestyle altering complications  
12    occur in single digit percents of  
13    patients. That's simply a difference of  
14    opinion. And I don't think it's a  
15    disconnect.

16          Q.     You've said before that you  
17    think that studies have not been powered  
18    to evaluate whether mesh slings create a  
19    long-term increase in adverse events. Do  
20    you recall that?

21          A.     I don't -- I don't recall it  
22    and it may have been taken out of  
23    context, but that's -- so the answer is,  
24    I don't recall it.

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1 Q. Let's talk about your  
2 salvage article that was marked as an  
3 exhibit a moment ago.

4 This is a peer-reviewed  
5 published article, right?

6 A. It is.

7 Q. And it was published in  
8 2013?

9 A. It is.

10 Q. So that's just a year ago,  
11 right?

12 A. It was a year ago it was  
13 published. Doesn't mean it was a year  
14 ago that it was written.

15 Q. Well, it was published in  
16 October of 2013 --

17 A. Yes.

18 Q. -- right?

19 So it was published in the  
20 latter part of 2015, right?

21 A. Yes.

22 Q. And you're saying now  
23 everything has changed for you with  
24 respect to the etiology of mesh

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1 complications, right?

2 MS. THOMPSON: Object to  
3 form. That misstates his  
4 testimony.

5 THE WITNESS: Yeah, I didn't  
6 say everything has changed. I was  
7 specifically asked if my opinions  
8 about the etiology have changed.  
9 And the answer is yes.

10 BY MR. MYERS:

11 Q. Well, you -- I guess what  
12 you said exactly is, you don't stand by  
13 what you said in your peer-reviewed  
14 publication about the etiology of mesh  
15 complications.

16 Is that fair?

17 MS. THOMPSON: Object to  
18 form. Misstates his testimony.

19 THE WITNESS: No. That's --  
20 that's not what I said.

21 BY MR. MYERS:

22 Q. Okay. Well, let's -- let's  
23 go through and make sure we get what you  
24 said because here's what I thought I



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1 heard.

2 Page 1284 says, "The  
3 etiology of mesh sling complications is a  
4 matter of conjecture." Right?

5 A. The use of the word  
6 "conjecture" in the --

7 Q. Hold on.

8 A. -- in the peer-reviewed  
9 literature is different than the use of  
10 the word "conjecture" in the legal sense.

11 In the legal sense I am  
12 obliged to, when I give an opinion, to --  
13 that it's -- that it's with a reasonable  
14 or high degree of medical certainty.

15 I can have the same high  
16 degree of medical certainty in a  
17 scientific journal, but I wouldn't state  
18 it like that because that's not the --  
19 there's a different context in the  
20 medical literature than there is in -- in  
21 the -- in the courtroom.

22 We do not use medical -- a  
23 high -- reasonable degree of medical  
24 certainty to come to conclusions. And

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1 the reason that we don't is that things  
2 that happen in the 4 or 5 percent range,  
3 which is -- let's just take that as one  
4 estimate of serious complications, things  
5 that happen that often in the -- you  
6 would never be able to say that within a  
7 reasonable degree of medical certainty  
8 something that happens 4 to 5 percent  
9 rises to a certain level in the  
10 peer-reviewed literature.

11 But I can say with a  
12 reasonable degree of medical certainty --  
13 I can -- let me say it another way.

14 I can offer a different  
15 opinion with a reasonable degree of  
16 medical certainty than I can in the  
17 peer-reviewed literature which requires,  
18 in my judgment, a higher degree of  
19 certainty than a reasonable degree.

20 So I phrase my words  
21 differently in the peer-reviewed  
22 literature than I do in the legal  
23 literature because it's two different  
24 sets of rules.

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1 MR. MYERS: I object and  
2 move to strike --

3 MS. THOMPSON: Object to the  
4 objection.

5 MR. MYERS: -- as  
6 non-responsive.

7 BY MR. MYERS:

8 Q. What you wrote in your  
9 peer-reviewed publication was, "The  
10 etiology of mesh sling complications is a  
11 matter of conjecture." Correct?

12 A. That's what I wrote, yes.

13 Q. And what you said 15 minutes  
14 ago was you no longer stand by that  
15 statement, correct?

16 MS. THOMPSON: Object to  
17 form. Misstates his testimony.

18 THE WITNESS: I think I  
19 already answered that.

20 MS. THOMPSON: And asked and  
21 answered.

22 BY MR. MYERS:

23 Q. Is that what you said or  
24 isn't it?

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1 I mean, I don't have to --  
2 if I misunderstood what you said, tell  
3 me.

4 A. I wrote --

5 MS. THOMPSON: Hang on.

6 Object. Asked and answered.

7 THE WITNESS: I believe I  
8 answered the question already.

9 You didn't like my answer  
10 and asked to strike it, but that's  
11 my answer.

12 BY MR. MYERS:

13 Q. No. No. You have -- no, I  
14 did not -- I didn't ask that question.  
15 So you -- you can't conduct a deposition  
16 this way. I'm sorry, Doctor. You have  
17 to answer the question.

18 A. I thought I did.

19 Can you say the question  
20 again, please?

21 And I don't mean to be  
22 disrespectful.

23 Q. Well, and I don't either.

24 But the question I asked you was whether

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1 that's what the sentence wrote. And  
2 that's -- and the page-long answer you  
3 gave had nothing to do with that.

4 A. I definitely answered it.

5 MS. THOMPSON: What is your  
6 question now?

7 BY MR. MYERS:

8 Q. The question now is whether  
9 you just testified, when counsel asked,  
10 that you no longer stand by the statement  
11 "The etiology of mesh sling complications  
12 is a matter of conjecture."

13 MS. THOMPSON: And -- hang  
14 on.

15 Object. It misstates his  
16 testimony. And it's been asked  
17 and answered.

18 THE WITNESS: I'm sorry, but  
19 I did answer it.

20 BY MR. MYERS:

21 Q. Well, you're going to have  
22 to answer it again.

23 MS. THOMPSON: No. That's  
24 his answer.

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1 MR. MYERS: Are you going --  
2 are you going to instruct him not  
3 to answer?

4 You're actually going to do  
5 that?

6 MS. THOMPSON: He answered  
7 the question.

8 MR. MYERS: He did not  
9 answer the question. He  
10 absolutely didn't.

11 You're going to instruct him  
12 not to answer on this?

13 MS. THOMPSON: I'm -- how  
14 many times does he need to answer  
15 it before --

16 MR. MYERS: He needs to  
17 answer --

18 MS. THOMPSON: -- he --

19 MR. MYERS: He needs to  
20 answer one of my questions today,  
21 at least, that I ask.

22 I'm allowed to ask  
23 questions, just like you were.

24 Are you instructing him not

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1 to answer?

2 MS. THOMPSON: I believe he  
3 has answered. I haven't  
4 instructed him to do anything.

5 MR. MYERS: Okay. Okay.

6 MS. THOMPSON: He can answer  
7 your question again, and he's  
8 going to answer it again.

9 BY MR. MYERS:

10 Q. Then answer the question.

11 MS. THOMPSON: Ask the  
12 question, and he'll answer it.

13 MR. MYERS: The question is  
14 asked.

15 MS. THOMPSON: He already  
16 answered your --

17 THE WITNESS: You read back  
18 to me -- you read back my -- what  
19 I wrote.

20 BY MR. MYERS:

21 Q. I'm just trying --

22 A. And I said that I did write  
23 that.

24 Q. No. That is not the

Jerry G. Blaivas, M.D.

1 question I even just asked.

2 The question I asked is  
3 whether I understood you to state earlier  
4 that you no longer stand by the  
5 statement.

6 MS. THOMPSON: Asked and  
7 answered. And misstates his  
8 testimony.

9 THE WITNESS: I'm sorry, but  
10 I -- I'll answer it again.

11 There is a different -- the  
12 words mean different things in the  
13 medical literature than they do in  
14 the legal literature.

15 In -- in the -- in this  
16 article, I bring up theoretical  
17 reasons why -- different reasons  
18 why complications can occur. I  
19 stand by that.

20 In the courtroom, you --  
21 okay. So I'll -- that's my answer  
22 to that.

23 BY MR. MYERS:

24 Q. So the issue is that the



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1 standard is different for the literature  
2 in the courtroom.

3 Is that fair?

4 A. Yes.

5 MS. THOMPSON: Object to  
6 form.

7 BY MR. MYERS:

8 Q. And by the standard you  
9 applied in the peer-reviewed literature,  
10 you made the statement that we just read.  
11 But by the standard you would apply to  
12 your testimony, you would not make that  
13 statement.

14 Fair?

15 MS. THOMPSON: Object to  
16 form.

17 THE WITNESS: I would say  
18 that within a reasonable degree of  
19 medical certainty, that what I  
20 already said before -- I'm just  
21 going to read this a second.

22 (Witness reviewing  
23 document.)

24 Yeah, within a reasonable

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1 degree of medical certainty, the  
2 reasons that I give in this paper,  
3 in the paper, are due to faulty  
4 mesh design.

5 BY MR. MYERS:

6 Q. Okay. And is the reason  
7 that you did not put those in your  
8 peer-reviewed article, again, because of  
9 the difference in the standard for a  
10 peer-reviewed article compared to the  
11 standard for legal testimony?

12 MS. THOMPSON: Object.

13 THE WITNESS: Well, I think  
14 there's two reasons.

15 Number one, there -- we  
16 didn't study that. Okay. We  
17 didn't -- we didn't study mesh  
18 design. So it would not have been  
19 part of our methods, and that's  
20 why we use -- that's where the  
21 words "conjecture" come from.

22 I mean, "conjecture"  
23 could -- could be -- could have  
24 been properly turned hypothesis

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1 simulated -- in simulations. And I  
2 actually did when -- I don't remember  
3 where, but I was a visiting professor in  
4 the days when you could still operate  
5 when you were a visiting professor.

6 So I scrubbed in on cases  
7 where they were being done. And I  
8 didn't -- and in that, it was using --  
9 I'm pretty sure it predated the Obtryx.  
10 But it was a similar design.

11 And I remember commenting on  
12 how I was uncomfortable with that feel,  
13 because I felt like I didn't have total  
14 control of the needle tip, whereas with  
15 the Curved I do.

16 And I don't think that's a  
17 matter of personal preference, I think  
18 it's just a different -- the way it's  
19 constructed. You know, the same motion  
20 with your hand can give you -- can have  
21 the needle move in different directions.  
22 Q. Can you identify any data to  
23 suggest that one version or the other of  
24 the handle of the Obtryx leads to more

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1 that Ross does unique examinations?  
2 MS. FITZPATRICK: Objection.  
3 THE WITNESS: I think it's  
4 plausible that Ross does a more  
5 thorough examination with respect  
6 to detecting banding than most  
7 other people do. Yes, I think  
8 that's plausible.

9 BY MR. MYERS:  
10 Q. But you have no evidence to  
11 demonstrate that, correct?

12 A. I'm just answering your  
13 question. No, I don't.

14 Q. So at this point in the  
15 deposition, you have been shown I think  
16 that AUGS and SUFU and IUGA and the FDA  
17 have all issued statements in support of  
18 the use and the safety of mid-urethral  
19 slings. Is there any data that you could  
20 be shown that would change your opinion?

21 A. My opinion with respect to  
22 what?

23 Q. The safety of mid-urethral  
24 slings.

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1 A. No, I don't even think we  
2 disagree about it. We dis -- as I've  
3 already testified, I think the people  
4 that wrote those articles would agree  
5 pretty much with my -- with the  
6 statistics that I have quoted. What they  
7 seem to disagree with is about how  
8 relevant that is to disclose that to  
9 patients. And I think that's a huge part  
10 of the problem, that it wasn't disclosed.

11 I don't think we disagree  
12 very much on this. I mean, we may  
13 quibble over percentage points whether  
14 it's one, two, three, four, five, six,  
15 but no one is going to say -- I would  
16 venture to say no one is going to say  
17 these lifestyle altering complications do  
18 not occur. Practically no one.

19 Q. I'm pretty confident that  
20 I'm not going to look on your website  
21 tomorrow and find a statement saying Dr.  
22 Blaivas supports the use of mid-urethral  
23 slings for stress urinary incontinence;  
24 is that correct?

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1 predating even the -- even the -- even  
2 the clinical trial.

3 I mean, to start with, okay,  
4 there's problems with, I alluded to  
5 before, with the ergonomics. Okay.

6 What they did, I have  
7 testified before, that even the slightest  
8 changes in design and ergonomics, and in  
9 the particular case of the -- for  
10 example, of the Boston Scientific, just  
11 making the dilator thicker, okay, or  
12 thinner, or making something, it changes  
13 the tactile sensation that the surgeon  
14 has in pulling it through.

15 It means that it's easier or  
16 harder to adjust the tension. It's  
17 easier or harder to perforate the bladder  
18 or the urethra or -- and particularly  
19 with the transobturator -- to perforate  
20 the vagina.

21 And to me, these are all  
22 things that should be tested before it  
23 goes to market, not afterwards. I mean,  
24 it's not good enough to just say, well,

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1 heard.

2 Page 1284 says, "The  
3 etiology of mesh sling complications is a  
4 matter of conjecture." Right?

5 A. The use of the word  
6 "conjecture" in the --

7 Q. Hold on.

8 A. -- in the peer-reviewed  
9 literature is different than the use of  
10 the word "conjecture" in the legal sense.

11 In the legal sense I am  
12 obliged to, when I give an opinion, to --  
13 that it's -- that it's with a reasonable  
14 or high degree of medical certainty.

15 I can have the same high  
16 degree of medical certainty in a  
17 scientific journal, but I wouldn't state  
18 it like that because that's not the --  
19 there's a different context in the  
20 medical literature than there is in -- in  
21 the -- in the courtroom.

22 We do not use medical -- a  
23 high -- reasonable degree of medical  
24 certainty to come to conclusions. And

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1 the reason that we don't is that things  
2 that happen in the 4 or 5 percent range,  
3 which is -- let's just take that as one  
4 estimate of serious complications, things  
5 that happen that often in the -- you  
6 would never be able to say that within a  
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8 something that happens 4 to 5 percent  
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11 But I can say with a  
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20 So I phrase my words  
21 differently in the peer-reviewed  
22 literature than I do in the legal  
23 literature because it's two different  
24 sets of rules.

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1 question I even just asked.

2           The question I asked is  
3 whether I understood you to state earlier  
4 that you no longer stand by the  
5 statement.

6           MS. THOMPSON: Asked and  
7 answered. And misstates his  
8 testimony.

9           THE WITNESS: I'm sorry, but  
10 I -- I'll answer it again.

11           There is a different -- the  
12 words mean different things in the  
13 medical literature than they do in  
14 the legal literature.

15           In -- in the -- in this  
16 article, I bring up theoretical  
17 reasons why -- different reasons  
18 why complications can occur. I  
19 stand by that.

20           In the courtroom, you --  
21 okay. So I'll -- that's my answer  
22 to that.

23 BY MR. MYERS:

24           Q.     So the issue is that the

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